ANTITACHYCARDIAL PACING

CROSS REFERENCE TO RELATED APPLICATIONS

1. This application is a continuation of application no. 09/231,570, filed January 14, 1999, now pending, which is a continuation-in-part of 08/699,552, filed August 19, 1996, now U.S. Patent no. 5,871,506. The 09/231,570 application and the '506 Patent are incorporated by reference herein, in their entireties, for all purposes.

INTRODUCTION

2. The present invention relates generally to implantable cardioverter/defibrillator with antitachycardial pacing capabilities and/or a method of such pacing.

BACKGROUND OF THE INVENTION

3. The typical implantable cardioverter/defibrillator (ICD) delivers an initial electrical countershock within ten to twenty seconds of arrhythmia onset, thereby saving countless lives. Improved devices have antitachycardia pacing capabilities in addition to cardioverting/defibrillating functions. These ICDs are capable of different initial responses to one or more tachycardia as well as a programmable sequence of responses to a particular arrhythmia.

4. The output energy level is generally set by a physician in accordance with a patient's capture threshold, determined at the time of heart implantation. This threshold represents the minimum pacing energy required to reliably stimulate a patient's heart. However, due to trauma associated with the stimulation, scar tissue grows at the interface between the implanted cardiac pacer leads and the myocardium. This scar tissue boosts the patient's capture threshold. To insure reliable cardiac capture, the output energy level is thus generally set at a level which is a minimum of two times greater than the initially measured capture threshold. A drawback to such an approach is that the higher stimulation level causes more trauma to the cardiac tissue than would a lower level of stimulation, and hence promotes the formation of scar tissue, thereby boosting the capture threshold.

5. The higher stimulation level also shortens battery life. This is not desirable, as a shorter battery life necessitates more frequent surgery to implant fresh batteries.

6. Another drawback is the potential for patient discomfort associated with this higher stimulation level. This is because the higher stimulation level can stimulate the phrenic or diaphragmatic plexus or cause intercostal muscle pacing.

7. Lastly, the higher stimulation is less effective, due to entry block.

8. A need therefore exists for an ICD that can achieve reliable cardiac capture with a lower stimulation level, thereby causing less damage to the heart, extending battery life, causing less pain to the patient and having greater therapeutic effectiveness than current ICDs. A need also exists for an ICD that can better entrain the heart and can entrain portions of the heart from a greater distance.

SUMMARY OF THE INVENTION

9. It therefore is an object of the present invention to provide an ICD with antitachycardial pacing capabilities, wherein the stimulation is administered with a voltage either at, just above, or just below the diastolic depolarization threshold potential.

10. It is another object of the present invention to sense whether cardiac capture has occurred, and if not, to administer additional stimulation.

11. It is another object of the present invention to provide the additional stimulation at a slightly higher voltage level than that level of stimulation which resulted in no capture.

12. It is another object of the present invention to repeat the stimulation - sensing cycle until cardiac capture has occurred.

13. It is another object of the present invention to provide stimulation using a biphasic waveform.

14. The present invention accomplishes the above objectives by providing an implantable cardioverter-defibrillator with a unique constellation of features and capabilities. Protocols disclosed include:

a) biphasic stimulation administered at, or just above, the diastolic depolarization threshold potential;

b) biphasic or conventional stimulation initiated at, or just above, the diastolic depolarization threshold potential, reduced, upon capture, to below threshold; and

c) biphasic or conventional stimulation administered at a level set just below the diastolic depolarization threshold potential.

15. As mentioned, the antitachycardial pacing protocols of the present invention can be used in conjunction with biphasic pacing. The method and apparatus relating to biphasic pacing comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape, and duration. In a preferred embodiment, the first and second phases have differing polarities. In one alternative embodiment, the two phases are of differing amplitude. In a second alternative embodiment, the two phases are of differing duration. In a third alternative embodiment, the first phase is in a chopped wave form. In a fourth alternative embodiment, the amplitude of the first phase is ramped. In a fifth alternative embodiment the first phase is administered over 200 milliseconds after completion of a cardiac beating/pumping cycle. In a preferred alternative embodiment, the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration, and the second phase of stimulation is a cathodal pulse of short duration and high amplitude. It is noted that the aforementioned alternative embodiments can be combined in differing fashions. It is also noted that these alternative embodiments are intended to be presented by way of example only, and are not limiting.

16. Enhanced myocardial function is obtained through the biphasic pacing of the present invention. The combination of cathodal with anodal pulses of either a stimulating or conditioning nature, preserves the improved conduction and contractility of anodal pacing while eliminating the drawback of increased stimulation threshold. The result is a depolarization wave of increased propagation speed. This increased propagation speed results in superior cardiac contraction leading to an improvement in blood flow and in increased access to reentrant circuits. Improved stimulation at a lower voltage level also results in reduction in scar tissue buildup thereby reducing the tendency of the capture threshold to rise; reduction in power consumption leading to increased life for pacemaker batteries; and decreased pain to the patient.

17. Additional objects and advantages of the present invention will be apparent in the following detailed description read in conjunction with the accompanying drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

18. Figs. 1A-1C illustrate examples of methodologies for treating arrhythmias.

19. Fig. 3 is a schematic representation of leading anodal biphasic stimulation.

20. Fig. 4 is a schematic representation of leading cathodal biphasic stimulation.

21. Fig. 5 is a schematic representation of leading anodal stimulation of low level and long duration, followed by conventional cathodal stimulation.

22. Fig. 6 is a schematic representation of leading anodal stimulation of ramped low level and long duration, followed by conventional cathodal stimulation.

23. Fig. 7 is a schematic representation of leading anodal stimulation of low level and short duration, administered in series followed by conventional cathodal stimulation.

DETAILED DESCRIPTION OF THE INVENTION

24. The present invention relates to the use of antitachycardial pacing to break up arrhythmia in the atrium. **Figs. 1A through 1C** illustrate examples of methodologies for treating arrhythmias.

25. **Fig. 1A** illustrates a first methodology. Here, a sensor senses the onset of arrhythmia **102**. In a preferred embodiment, this sensor comprises an antitachycardial pacing algorithm. Biphasic stimulation is then administered **104**. In varying embodiments, this stimulation is either at, or just above the diastolic depolarization threshold. The ICD determines whether capture has occurred **106**. If capture has not occurred, then stimulation continues at a slightly higher level **108**. This stimulation - capture check - boost stimulation cycle continues until capture occurs. If capture has occurred, then stimulation is continued for a predetermined period of time **110**. In a preferred embodiment, stimulation is administered as long as the arrhythmia persists.

26. In a preferred embodiment, stimulation pulses are administered at 80 to 100 percent of the intrinsic rate with an approximately one to two second pause between each set of stimulation pulses. Then either the number of pulses increases, or the timing between pulses is adjusted. For example, in a preferred embodiment, the first pulse sequence can be at 80 percent of the intrinsic heart rate, the second pulse sequence at 82 percent, the third pulse sequence at 84 percent, and so on. In a preferred embodiment a

plurality of feedback loops provide data such that the voltage can be adjusted to constantly skirt the capture threshold. Stimulation is continued until the rhythm reverts.

27. **Fig. 1B** illustrates a second methodology. Here, a sensor senses the onset of arrhythmia **112**. In varying embodiments of the second method, either biphasic or conventional stimulation is then administered **114**. This stimulation level is set at or just above the diastolic depolarization threshold potential. The ICD determines whether capture has occurred **116**. If capture has not occurred, then stimulation continues at a slightly higher level **118**. This stimulation - capture check - boost stimulation cycle continues until capture occurs. If capture has occurred, then stimulation is gradually and continuously reduced to below threshold, and continued **120**. Then, if capture is lost, the stimulation is raised to a slightly higher level and is again gradually and continuously reduced. This entire sequence is repeated, such that the stimulation level hovers as close as possible to the lowest stimulation level which provides capture. Stimulation continues until the rhythm reverts, for example, when the antitachycardial pacing algorithm determines that pacing is no longer necessary.

28. **Fig. 1C** illustrates a third methodology. Here, a sensor senses the onset of arrhythmia **122**. In varying embodiments of the third method, either biphasic or conventional stimulation is then administered **124**. This stimulation level is set just below the diastolic depolarization threshold potential. The ICD determines whether capture has occurred **126**. If capture has not occurred, then stimulation continues at a slightly higher level **128**. This stimulation - capture check - boost stimulation cycle continues until capture occurs. If capture has occurred, then stimulation is continued at below threshold level **130**. If capture is lost then the stimulation is raised to a slightly higher level and is gradually and continuously reduced. This entire sequence is repeated, such that the stimulation level hovers as close as possible to the lowest stimulation level which provides capture. Stimulation continues until the rhythm reverts, for example, when the antitachycardial pacing algorithm determines that pacing is no longer necessary.

Sensing

29. Sensing can be direct or indirect. For example, direct sensing can be based on data from sensing electrodes. The ICD of the present invention includes sensing

circuits/electronics to sense an arrhythmia through one or more sensing and/or stimulating electrodes. The sensing electronics sense the cardiac activity as depicted by electrical signals. For example, as is known in the art, R-waves occur upon the depolarization of ventricular tissue and P-waves occur upon the depolarization of atrial tissue. By monitoring these electrical signals the control/timing circuit of the ICD can determine the rate and regularity of the patient's heart beat, and thereby determine whether the heart is undergoing arrhythmia. This determination can be made by determining the rate of the sensed R-waves and/or P-waves and comparing this determined rate against various reference rates.

30. Direct sensing can be based upon varying criteria; such as, but not limited to, primary rate, sudden onset, and stability. The sole criteria of a primary rate sensor is the heart rate. When applying the primary rate criteria, if the heart rate should exceed a predefined level, then treatment is begun. Sensing electronics set to sudden onset criteria ignore those changes which occur slowly, and initiate treatment when there is a sudden change such as immediate paroxysmal arrhythmia. This type of criteria would thus discriminate against sinus tachycardia. Stability of rate can also be an important criteria. For example, treatment with a ventricular device would not be warranted for a fast rate that varies, here treatment with an atrial device would be indicated.

31. In alternative embodiments, sensing can be indirect. Indirect sensing can be based on any of various functional parameters such as arterial blood pressure, rate of the electrocardiogram deflections or the probability density function (pdf) of the electrocardiogram. For example, whether or not to administer treatment can also be affected by pdf monitoring of the time the signal spends around the baseline.

32. Sensing can also be augmented by stimulating the atria and observing and measuring the consequent effects on atrial and ventricular function.

33. Thus, in a preferred embodiment, sensing electronics are based upon multiple criteria. In addition, the present invention envisions devices working in more than one chamber such that appropriate treatment can be administered to either the atrium or the ventricle in response to sensing electronics based upon a variety of criteria, including those described above as well as other criteria known to those skilled in the art.

Stimulation

34. Electrical stimulation is delivered via lead(s) or electrode(s). These leads can be epicardial (external surface of the heart) or endocardial (internal surface of the heart) or any combination of epicardial and endocardial. Leads are well known to those skilled in the art; see, for example, United States Patent Nos. 4662377 to Heilman et al., 4481953 to Gold et al., and 4010758 to Rockland et al., each of which is herein incorporated by reference in its entirety.

35. Lead systems can be unipolar or bipolar. A unipolar lead has one electrode on the lead itself, the cathode. Current flows from the cathode, stimulates the heart, and returns to the anode on the casing of the pulse generator to complete the circuit. A bipolar lead has two poles on the lead a short distance from each other at the distal end, and both electrodes lie within the heart.

36. Conventional stimulation is well known to those skilled in the art and comprises monophasic waveforms (cathodal or anodal) as well as multiphasic waveforms wherein the nonstimulating pulses are of a minimal magnitude and are used, for example, to dissipate a residual charge on an electrode.

37. **Figs. 3 through 7** depict a range of biphasic stimulation protocols. These protocols have been disclosed in United States Patent Application No. 08/699,552 to Mower, which is herein incorporated by reference in its entirety.

38. **Fig. 3** depicts biphasic electrical stimulation wherein a first stimulation phase comprising anodal stimulus **302** is administered having amplitude **304** and duration **306**. This first stimulation phase is immediately followed by a second stimulation phase comprising cathodal stimulation **308** of equal intensity and duration.

39. **Fig. 4** depicts biphasic electrical stimulation wherein a first stimulation phase comprising cathodal stimulation **402** having amplitude **404** and duration **406** is administered. This first stimulation phase is immediately followed by a second stimulation phase comprising anodal stimulation **408** of equal intensity and duration.

40. **Fig. 5** depicts a preferred embodiment of biphasic stimulation wherein a first stimulation phase, comprising low level, long duration anodal stimulation **502** having

amplitude **504** and duration **506**, is administered. This first stimulation phase is immediately followed by a second stimulation phase comprising cathodal stimulation **508** of conventional intensity and duration. In differing alternative embodiments, anodal stimulation **502** is: 1) at maximum subthreshold amplitude; 2) less than three volts; 3) of a duration of approximately two to eight milliseconds; and/or 4) administered over 200 milliseconds post heart beat. Maximum subthreshold amplitude is understood to mean the maximum stimulation amplitude that can be administered without eliciting a contraction. In a preferred embodiment, anodal stimulation is approximately two volts for approximately three milliseconds duration. In differing alternative embodiments, cathodal stimulation **508** is: 1) of a short duration; 2) approximately 0.3 to 1.5 milliseconds; 3) of a high amplitude; 4) in the approximate range of three to twenty volts; and/or 5) of a duration less than 0.3 millisecond and at a voltage greater than twenty volts. In a preferred embodiment, cathodal stimulation is approximately six volts administered for approximately 0.4 millisecond. In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this specification, a maximum membrane potential without activation is achieved in the first phase of stimulation.

41. **Fig. 6** depicts an alternative preferred embodiment of biphasic stimulation wherein a first stimulation phase, comprising anodal stimulation **602**, is administered over period **604** with rising intensity level **606**. The ramp of rising intensity level **606** can be linear or non-linear, and the slope can vary. This anodal stimulation is immediately followed by a second stimulation phase comprising cathodal stimulation **608** of conventional intensity and duration. In alternative embodiments, anodal stimulation **602**: (1) rises to a maximum subthreshold amplitude less than three volts; (2) is of a duration of approximately two to eight milliseconds; and/or (3) is administered over 200 milliseconds post heart beat. In yet other alternative embodiments, cathodal stimulation **608** is: (1) of a short duration; (2) approximately 0.3 to 1.5 milliseconds; (3) of a high amplitude; (4) in the approximate range of three to twenty volts; and/or (5) of a duration less than 0.3 milliseconds and at a voltage greater than twenty volts. In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this

specification, a maximum membrane potential without activation is achieved in the first phase of stimulation.

42. **Fig. 7** depicts biphasic electrical stimulation wherein a first stimulation phase, comprising series **702** of anodal pulses, is administered at amplitude **704**. In one embodiment, rest period **706** is of equal duration to stimulation period **708**, and is administered at baseline amplitude. In an alternative embodiment, rest period **706** is of a differing duration than stimulation period **708**, and is administered at baseline amplitude. Rest period **706** occurs after each stimulation period **708**, with the exception that a second stimulation phase, comprising cathodal stimulation **710** of conventional intensity and duration, immediately follows the completion of series **702**. In alternative embodiments: (1) the total charge transferred through series **702** of anodal stimulation is at the maximum subthreshold level; and/or (2) the first stimulation pulse of series **702** is administered over 200 milliseconds post heart beat. In yet other alternative embodiments, cathodal stimulation **710** is: (1) of a short duration; (2) approximately 0.3 to 1.5 milliseconds; (3) of a high amplitude; (4) in the approximate range of three to twenty volts, and/or (5) of a duration less than 0.3 milliseconds and at a voltage greater than twenty volts.

Determining Cardiac Capture

43. Capture can be determined by multiple means. First, capture or the loss thereof, can be determined by monitoring cardiac rhythm. Loss of capture can result in a change in timing of the heart beat.

44. Second, capture can be monitored through the development of a template. The template can be based on parameters such as electrocardiogram data, mechanical motion and/or probability density function data. Where the template is established pre-stimulation, a change in the baseline signifies capture. Where the template is established after capture has occurred, a change in the template characteristics signifies loss of capture. The templates can be established and/or updated at any time.

45. Once capture occurs the stimulation protocol of the entrained sites is adjusted as illustrated by Figs. 1A through 1C.

46. Having thus described the basic concept of the invention, it will be readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to be presented by way of example only, and is not limiting. Various alterations, improvements and modifications will occur and are intended to those skilled in the art, but are not expressly stated herein. These modifications, alterations and improvements are intended to be suggested hereby, and within the scope of the invention. Further, the pacing pulses described in this specification are well within the capabilities of existing pacemaker electronics with appropriate programming. Accordingly, the invention is limited only by the following claims and equivalents thereto.

47. The present invention has been described in terms of preferred embodiments, however, it will be appreciated that various modifications and improvements may be made to the described embodiments without departing from the scope of the invention.